UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	**MDL No. 1456** **Master File No. 01-12257-PBS** **Subcategory Case No. 06-11337**
THIS DOCUMENT RELATES TO: *State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc. et al.*, Civil Action No. 03-11226-PBS	**Hon. Patti B. Saris**

DEFENDANTS' JOINT BRIEF IN OPPOSITION TO
PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

As its moving papers make clear, California is using this action to rewrite the Medi-Cal program's pharmacy reimbursement history and the federal statute requiring that Medicaid payments be sufficient to ensure access to quality care. The center point of California's arguments on its summary judgment motion is the fiction that it only ever intended to reimburse providers at an amount equal to the "Cost of the Drug Product" for the Subject Drugs. (*See* November 23, 2009 Declaration of Kevin Gorospe ("Gorospe Decl."), at ¶ 5.) Extensive evidence in the record contradicts this premise, creating numerous issues of fact, and thus mandating denial of California's motion.[1]

Even today, more than four years after California originally intervened in this lawsuit, California calculates reimbursement payments by paying providers at the published compendia AWP minus 17 percent, with full knowledge that the compendia AWP does not reflect actual acquisition cost and that the resulting payments significantly exceed providers' actual costs for drugs. In fact, this summer, the United States District Court for Central District of California enjoined California from implementing a five percent reduction in the rate it pays on the grounds that the reduction in payments may drive Medi-Cal providers from the program and adversely impact Medi-Cal beneficiaries' access to quality medical care. *See* Robben Decl. Ex. 46, at 5-18.

[1] The abbreviated citations herein are defined as follows: "Robben Decl." refers to the Declaration of Philip D. Robben In Support of Defendants' Motions for Partial Summary Judgment, dated Nov. 25, 2009 (Dkt. No. 6702) and the Declaration of Philip D. Robben In Opposition to Plaintiff State of California's Motion for Summary Judgment, dated Dec. 21, 2009; "Joint SOF" refers to the Defendants' Joint Statement of Undisputed Material Facts in Support of their Motions for Partial Summary Judgment, dated November 25, 2009 (Dkt. No. 6703); "Joint Brief" refers to Defendants' Joint Brief in Support of their Motions for Partial Summary Judgment, dated November 25, 2009 (Dkt. No. 6710); "Opp." refers to Plaintiffs' Opposition to Defendants' Joint Brief in Support of their Motions for Partial Summary Judgment, dated Dec. 21, 2009; "Mylan Counterstatement" refers to Defendants Mylan Inc. and Mylan Pharmaceuticals Inc.'s Individual Statement in Opposition to Plaintiff's Statement of Undisputed Material Facts as to the Mylan Defendants, dated Dec. 21, 2009; "Dey Counterstatement" refers to Defendants Dey, Inc. and Dey, L.P.'s Individual Statement in Opposition to Plaintiff's Statement of Undisputed Material Facts as to the Dey Defendants, dated Dec. 21, 2009; "Sandoz Counterstatement" refers to Defendant Sandoz Inc.'s Individual Statement in Opposition to Plaintiff's Statement of Undisputed Material Facts as to Sandoz, dated Dec. 21, 2009.

In a declaration he submitted in opposition to the injunction in that action, Kevin Gorospe, the Chief of the Medi-Cal Pharmacy Policy Unit at California's Department of Health Services ("DHS") since 2000 and California's leading witness in this action, did not describe the AWP minus 17 percent reimbursement payment as the "Cost of the Drug Product," as he did in his declaration in support of this motion. (Gorospe Decl. at ¶5.) To the contrary, Mr. Gorospe declared that the reduction would not jeopardize access because Medi-Cal's pharmacy reimbursement payments are "well above" providers' actual costs: "[I]t is because the Medi-Cal reimbursement for the drug itself frequently is well above pharmacy acquisition cost, that any loss on the dispensing fee portion of reimbursement is made up for by a significant profit on Medi-Cal reimbursement for the drug itself." Joint SOF at ¶ 67. Despite Mr. Gorospe's pronouncements about the profits Medi-Cal pays on prescription drug reimbursement, the District Court granted the injunction, relying on controlling Ninth Circuit precedent requiring that California's payments be consistent with efficiency, economy, and access to quality care. *See* Robben Decl. Ex. 46, at 7-18.

Mr. Gorospe's contradictory declarations alone create an issue of fact requiring denial of California's motion for summary judgment. California cannot ask for summary judgment on False Claims Act claims in one federal court on the premise that it only ever intended to pay providers their actual costs for drugs, while in another federal court have its Chief of Pharmacy Policy tout the profits paid on the drug cost portion of its pharmacy reimbursements to rationalize adjustments to its reimbursement payments. Indeed, Mr. Gorospe's conflicting statements, and the thorny issues they raise in light of the controlling Ninth Circuit precedent governing Medi-Cal pharmacy reimbursement payments, make remanding this action back to a federal court in California all the more compelling.

California's continued reliance on compendia AWP as a reimbursement basis, Mr. Gorospe's conflicting declarations, and the pending injunction, make up only the tip of the iceberg of evidence in the record that refutes California's claim that, as a matter of law, it only ever intended to pay providers their actual costs for the Subject Drugs. The record raises, at the very least, a question of fact as to whether what California alleges are "overpayments" for the Subject Drugs were the result of knowing and deliberate policy decisions made by California, rather than some corruption of the reimbursement system caused by Defendants' price reporting practices.

A. California's Definition of "AWP"

California has never defined AWP in a statute or regulation as anything other than "the price for a drug product listed for a standard package in the Department's primary price reference source." *See* Joint SOF at ¶ 20. Noticeably absent from this definition is any indication that AWP should represent a fully discounted net price, or should otherwise approximate a providers' actual cost to acquire a drug. Indeed, there is nothing in this definition that indicates how AWP should be determined or calculated at all.

In contrast to California's silence concerning AWP, other pricing terms used in the Medicaid pharmacy reimbursement context have clear and express definitions. For instance, throughout the relevant time period, Defendants have reported Average Manufacturer Prices ("AMPs") to CMS on a quarterly basis for all of the Subject Drugs. Since January 1, 1991, federal law has required all drug manufacturers, including Defendants, to enter into a rebate agreement with the United States Secretary for Health and Human Services, on behalf of all states (the "Rebate Agreement") in order for their drugs to be covered under the Medicaid program. *See* 42 U.S.C.A. § 1396r-8(a)(1), (a)(2). The Rebate Agreement requires Defendants to report AMPs for all of their drugs that are reimbursed under the Medicaid program to CMS on

a quarterly basis. Mylan Counterstatement at Resp. 10; Dey Counterstatement at Resp. 7. The Rebate Agreement defines AMP as "the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade" and specifically requires that AMP take into account "cash discounts allowed and all other price reductions … which reduce the actual price paid." Mylan Counterstatement at Resp. 10; Dey Counterstatement at Resp. 7. CMS uses the AMPs it receives from Defendants to calculate the Unit Rebate Amount, or URA, an NDC-specific, per-unit amount. Dey Counterstatement at Resp. 7. For multisource generic drugs such as the Subject Drugs, the URA is calculated as 11% of the AMP. *See* 42 U.S.C.A. 1396r-8(c)(3)(A – B). CMS forwards the URAs on to state Medicaid programs, including the Medi-Cal program, who in turn multiply the URAs by the number of units dispensed to determine the final rebate amount Defendants will pay. Dey Counterstatement at Resp. 7. The state Medicaid programs then send Defendants invoices for the rebate amounts owed. Dey Counterstatement at Resp. 7.

California itself has defined other pricing terms to be used in the Medicaid context. The terms are defined in statutes in a manner that gives clear guidance as to what is expected to be reported. For instance, in August 2004, in an effort to revise its reimbursement methodology, the California legislature amended California Welfare and Institutions Code § 14105.45 to include the pricing term "Average Sales Price," or "ASP." *See* CAL. WELF. & INST. CODE § 14105.45 (a)(1) (2004). The statute defines ASP as "[t]he manufacturer's sales to all purchasers, … of a drug or biological in the United States in the calendar quarter, divided by the total number of the units of that drug or biological sold by the manufacturer in that calendar quarter." *Id.* at (a)(1)(A). In calculating ASP, the statute directed manufacturers to take into account "volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase

requirement, chargebacks, and rebates…" *Id.* at (a)(1)(C). The statute, as amended, required manufacturers to report ASPs to Medi-Cal on a quarterly basis, and anticipated that ASPs would be used to calculate pharmacy reimbursement payments. *Id.* at (a)(12), (b)(2). Although Medi-Cal never actually implemented a reimbursement methodology based on ASP, California's ability to enact the definition in a statute demonstrates that it could have easily done the same for AWP, but chose not to. Indeed, the same statute that defined ASP continued to define AWP only as "the price for a drug product listed for a standard package in the Department's primary price reference source." *Id.* at (a)(2).

Similarly, in September 2002, California enacted California Welfare and Institutions Code § 14105.47 to govern the establishment of maximum allowable costs to be paid by the Medi-Cal program, including maximums for drug reimbursements. The statute provides that the maximum cost for a given product shall be based on the "mean of the wholesale selling price of related medical supply products that are available in California." CAL. WELF. & INST. CODE § 14105.47 (b)(3)(C) (2007). The statute defines "wholesale selling price" ("WSP") as "the price, including discounts and rebates, paid by a provider to a wholesaler, distributor, or manufacturer for a medical supply product." *Id.*

B. California's Understanding of AWP

Massive evidence in the record shows that California knew that published AWPs significantly exceeded costs for drugs, especially generic drugs such the Subject Drugs. Reports prepared by California and on California's behalf reflect California's knowledge of the difference between AWP and providers' actual costs:

- In 1977, the California Department of Finance issued a report on Medi-Cal price controls for pharmacy reimbursement. Joint SOF at ¶ 23. The study noted that: "The range of discounts among pharmacies [off of AWP] is unknown but probably is from 8 to 25

percent or more…" and that "[t]he actual acquisition cost of individual pharmacies has no bearing upon the payment Medi-Cal makes."

- In 1985, HCFA issued a report documenting a California-focused study comparing published AWPs to actual acquisition costs for pharmacists across the state. Joint SOF at ¶ 24. The report noted that: "AWPs are not determined by surveying market transactions and thus do not accurately reflect prices pharmacists pay for drug products." *Id.* The report also found that California pharmacists could purchase drugs generally at an average discount 16 percent off of AWP, and could purchase generic drugs specifically at an average discount 22 percent off of AWP. *Id.*

- When evaluating the adoption of HCFA's 1987 FUL regulations, California collected market place contract pricing information on generic drugs which showed the differences between contract prices available to retail pharmacies on generic drugs and published prices. Joint SOF at ¶ 26. Indeed, in the Final Statement of Reasons supporting the adoption of the regulations, California noted that its reimbursement methodology, which at that time was calculated using an undiscounted AWP, would result in a payment for a particular generic drug of more than double the providers' actual cost. *Id.*

- In 1989 HCFA issued another report examining the relationship between AWP and providers' actual costs and found that one wholesaler's catalog offered prices on an average of 30 percent below AWP and that, on average, providers could acquire generic drugs at approximately 18 percent below AWP. Joint SOF at ¶ 27. The same report quoted a wholesaler representative describing AWP as "a meaningless figure" and a Pennsylvania Medicaid official stating that AWP "… just doesn't mean anything. It has no connection to what pharmacies really purchase the drugs for." *Id.* Two years later, the California Auditor General specifically cited the findings in this report in another report discussing California's adoption of an AWP minus five percent reimbursement methodology. Joint SOF at ¶ 28.

- In 1996, the HHS-OIG conducted a California-specific survey of pharmacy acquisition costs and concluded that California pharmacists could acquire single-source drugs, on average, at a discount of AWP minus 17 percent, and could acquire multi-source drugs, on average, at a discount of AWP minus more than 40 percent. Joint SOF at ¶¶ 29-32.

- In 2002, Myers & Stauffer issued the results of its state-wide survey of California pharmacists' actual acquisition costs for generic drugs. Joint SOF at ¶¶ 42-44. The survey found that California pharmacists could purchase single-source drugs for, on average, 17 percent below AWP; multi-source drugs without an FUL for, on average, 44 percent below AWP; and multi-source drugs with an FUL for, on average 87 percent below AWP. *Id.* The Myers & Stauffer report also compared AWPs to actual acquisition costs for 78 of the Subject Drugs, in many instances showing "spreads" of more than 1000 percent. Joint SOF at ¶ 45.

Supplementing these reports are a host of reports prepared by the federal government, dating back to the early 1980s, documenting that AWP is not a reliable predictor of actual acquisition cost, particularly for generic drugs.[2]

Medi-Cal officials responsible for the pharmacy program understood throughout the relevant time period that AWP was not a reliable indicator of prices for drugs, particularly for generic drugs. Kevin Gorospe, Chief of the Medi-Cal Pharmacy Policy Unit at DHS since 2000 and the individual who submitted the declaration in the case in the Central District of California, confirmed that he understood as early as the late 1990s that AWP minus 20 percent was "significantly higher than pharmacy acquisition costs for generic drugs." Joint SOF at ¶ 38. Len Terra, Mr. Gorospe's predecessor at DHS, confirmed that, since at least 1985, "it was generally known in the pharmacist industry that AWP did not reflect actual acquisition costs by pharmacists." Joint SOF at ¶ 39.

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[2] *See e.g.* HHS-OIG, *Medicaid Action Transmittal No. 84-12* at 3, 6 ("AWP represents a list price and does not reflect several types of discounts, such as prompt payment discounts, total order discounts, . . . rebates, or free goods that do not appear on the pharmacist's invoices. . . .") (Robben Decl. Ex. 51); HHS-OIG, *Physicians' Costs for Chemotherapy Drugs* at 5 (Nov. 1992) (Robben Decl. Ex. 52) ("Red Book officials confirmed that AWP is not designed to reflect physicians' costs."); HHS-OIG, *Medicaid Pharmacy – Actual Acquisition Cost of Generic Prescription Drug Products* (A-06-97-00011) (Aug. 1997) (Robben Decl. Ex. 53) (finding that pharmacists' actual acquisition costs for the 200 generic drugs with the highest amount of Medicaid reimbursement in 1994 and 1995 were, on average, 42.5% less than the AWPs reported in pricing publications); HHS-OIG, *Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products* at WI-Prod-AWP-112295 (Mar. 14, 2002) (Robben Decl. Ex. 54) (finding that the actual acquisition cost for generic drugs was a national average of 65.93 percent below AWP); HHS-OIG, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products* at 4 (Sept. 16, 2002) (Robben Decl. Ex. 55) (finding that pharmacies purchased single source innovator drugs at 17.2 percent below AWP; drugs without FULs at 27.2 percent below AWP; multiple source drugs without FULs at 44.2 percent below AWP; and multiple source drugs with FULs at 72.1 percent below AWP, and recommending that, if a state must use AWP as a basis for reimbursement, it should adopt a four-tiered reimbursement system to bring pharmacy reimbursement more in line with the actual acquisition costs); HHS-OIG, *State Strategies to Contain Medicaid Drug Costs* at 8-9 (Oct. 2003) (Robben Decl. Ex. 56) (finding that "AWP overstated pharmacy acquisition costs for brand name drugs by 22% and overstated acquisition costs for generic drugs by 66%.").

C. The 1987 Federal Regulations Governing Medicaid Drug Reimbursement

To support its claim that it could only ever pay providers its best estimate of their actual cost, California cites to federal regulations governing the calculation of the Estimated Acquisition Cost ("EAC"). *See* Opp. at 5, (*citing* 42 C.F.R. § 447.301). California's entire argument employs Medicaid policy from 1977 that applies EAC on a drug-by-drug basis. However, the regulations governing EAC and how it is applied were thoroughly revised in 1987. *See* 42 C.F.R. § 447.331; Fed. Reg. Vol. 52, No. 147, July 31, 1987, at pp. 28648-58. HCFA's own summary of the 1987 regulations confirms the rules were changed to account for and take advantage of declining generic prices:

> "This rule *eliminates current Departmental procedures for setting limits or payments for drugs . . . and reverses Medicaid rules … .* This rule enables the Federal and State governments to take advantage of savings that are currently available in the market place for [generic] drugs.

(Fed. Reg. Vol. 52, No. 147, July 31, 1987, at p. 28648 (emphasis added); *see also id*. "B. Other Drugs," at p. 28654.)

The "Departmental procedures" that were "eliminate[d]" in the 1987 regulations are the same policies from 1977 that required the ingredient and dispensing fee portions of reimbursement to be evaluated separately and on a drug-by-drug basis. The revised regulations – which are the regulations that were in effect throughout the relevant time period from January 1, 1994 to December 31, 2004 – limited aggregate reimbursement payments for certain multi-source drugs with upper limits – known as Federal Upper Limits ("FULs") – to the FULs plus a reasonable dispensing fee, and limited payments for all other drugs "in the aggregate" to EAC plus a reasonable dispensing fee. *See* 42 C.F.R. §§ 447.331, 447.332. As the HCFA stated, "[u]nder this rule, the EAC criteria are applied as an upper limit on an aggregate basis rather than on a prescription by prescription basis." (*See* Fed. Reg. Vol. 52, No. 147, July 31, 1987, at p.

28652.) As a result, states are permitted by the federal government to make higher payments for some drugs as long as those higher payments are offset by lower payments for other drugs:

> 1. Increased State Flexibility
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> * * *
>
> Under these final regulations, State agencies will be able to make higher payments for some listed drugs as long as they pay at rates lower than those listed for other drugs on the list. … Similarly, State agencies may employ essentially the same approach in meeting the limits for all other drugs. That is, the same principal [*sic*] of balancing payment increases for some drugs with decreases for other drugs also applies in determining whether aggregate payments exceed the limit.

(Fed. Reg. Vol. 52, No. 147, July 31, 1987, at p. 28655.)[3]

Furthermore, as the federal government stated in its comments to the 1987 regulations, this change in the law explicitly acknowledges that states are allowed to build a profit margin into reimbursement to encourage pharmacists to use lower priced generic drugs and acknowledges the use of extensive discounting from benchmark prices:

> In the previous section, we discussed the possible effects of building into our rates for ingredients a profit margin for pharmacists. We expressed the hope that States would recognize the advantage of providing pharmacies with an incentive to participate in the Medicaid program and to stimulate pharmacies to engage in prudent purchasing practices and the substitution of lower cost therapeutically equivalent products.
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> * * *
>
> [W]e suspect that price competition would be carried on in the form of discounts, promotional campaigns and other incentives

[3] Moreover, when determining whether a state's pharmacy reimbursement payments comply with the federal aggregate upper limits, the regulations require that ingredient payments be considered together with a *reasonable* dispensing fee, not necessarily the dispensing fee actually paid by the state. *See* Robben Decl., Ex. 57, at 7. ("We conclude that the regulations permit a state to use an amount other than the dispensing fee it actually paid in calculating the upper payment limit.") Thus, states – including California – could offset inadequate dispensing fee payments with ingredient portion payments that exceeded the limits set by the regulations, so long as, in the aggregate, the resulting payments did not exceed the ingredient limits plus a reasonable dispensing fee. *See id.* at 8.

> aimed at the retail pharmacists. … [O]ur policy of using published prices as a basis for determining payment levels may cause wholesalers to invent new ways of offering discounts to smaller independent retail outlets, thereby expanding the practice of discounting to those outlets and enabling them to have access to less expensive sources of pharmaceuticals. . . .

(Fed. Reg. Vol. 52, No. 147, July 31, 1987, at p. 28656.) HCFA acknowledged, moreover, that the reported prices "overstated" actual costs. Fed. Reg. Vol. 52, No. 147, July 31, 1987, at p. 28650.

D. California's Policy Decisions Concerning Reimbursement

As discussed above, the record shows that California has been aware since at least the 1970s that compendia AWPs exceed providers' actual acquisition costs significantly, especially for generic drugs, and that reimbursement payments made based on AWP result in margins above providers' actual cost. *See supra* at 5-7. The record also shows that, for a variety of policy reasons, California has repeatedly rejected proposals to bring its reimbursement payments closer in line to providers' actual cost for drugs, and has instead knowingly and deliberately adopted reimbursement methodologies that, even today, pay providers large margins above cost for generic drugs:

- In 1986, in response to a survey conducted by HCFA that found that pharmacists could acquire generic drugs at an average discount of 22.14 percent below AWP, John Rodriguez, at the time the Deputy Director of Medical Care Services at DHS, expressed skepticism about the value of attempting to reduce payments to more closely approximate providers' costs:

  > [W]e would like to remind HCFA that successfully "tightening up" our EAC program will concomitantly result in enormous pressure for California's Medi-Cal program to upgrade the dispensing fee. This is exactly what occurred when we originally implemented our EAC program. Such a development may well result in no significant change in overall drug costs. If, in fact, costs are only shifted, is a change in federal regulations or more aggressive enforcement of existing EAC regulations really cost effective?

Joint SOF at ¶ 24-25.

- When it adopted the 1987 federal regulations implementing the FUL program, California noted with approval that the revised methodology would pay a provider more than double his actual cost for a generic drug (resulting in a "spread" of more than 100 percent), citing to a mutual benefit to both the provider and the Medi-Cal program:

> Not only did the pharmacist increase his margin by $3.40 when dispensing the generic drug product over the brand name product; but, by placing an upper limit of reimbursement, Medi-Cal saved $15.15, which is more than 50% of the reimbursement amount for the brand name product.

Joint SOF at ¶ 26.

- In 1996, California received a report prepared by HHS-OIG that indicated that pharmacists could acquire single-source brand drugs at an average discount of 17 percent below AWP, and multi-source drugs at an average discount of 41.4 percent below AWP. Joint SOF at ¶ 32. On multiple occasions following the publication of the report, California considered revising its reimbursement methodology to reduce payments for drugs (albeit to levels that still exceeded providers' actual acquisition costs as indicated by the HHS-OIG report). Joint SOF at ¶¶ 33, 35-36. However, each time such a proposal was made, concerns were raised that the reduced payments would cause providers to disenroll from the program, thereby creating serious access issues for Medi-Cal beneficiaries. *Id.* None of these proposals were ever adopted. *Id.*

- In 2000, First DataBank began to publish "revised" AWPs, calculated by the National Association of Medicaid Fraud Control Units ("NAMFCU") and the United States Department of Justice ("DOJ") based on actual market prices. (Dey SOF at ¶ 37-38.) NAMFCU and DOJ calculated DOJ AWPs, as they came to known, for Dey's acetylcysteine, albuterol sulfate, cromolyn sodium, and metaproterenol, all of which are Subject Drugs in this action. *Id.* Despite having access to these new, revised AWPs that were significantly below the previously published AWPs, California elected not to implement them and instead continued to reimburse based on the old AWPs, again citing concerns that reduced payments would create access problems for Medi-Cal beneficiaries. (Dey SOF at ¶¶ 39-40.)

- In 2002, following the receipt of the Myers and Stauffer report and the relator's first amended *qui tam* complaint (both of which showed spreads for some of the Subject Drugs of over 1000 percent) DHS proposed revising the Medi-Cal reimbursement methodology from AWP minus five percent to AWP minus 10 percent. (Joint SOF at ¶¶ 45, 50-53, 61, 63.) Originally, DHS had proposed setting the reimbursement rate for generic drugs at AWP minus 40 percent, but, citing concerns raised by the California Pharmacists Association regarding continued provider enrollment and access, DHS dropped the separate, lower rate for generics and instead proposed AWP minus 10

percent for all drugs. Joint SOF at ¶ 52. The California legislature adopted this revised methodology. Joint SOF at ¶ 53.

- In 2004, California again revised its reimbursement methodology to AWP minus 17 percent, and increased the dispensing fee from $4.05 to $7.25. Joint SOF at ¶ 54. DHS endorsed this change, despite recognizing that the resulting reimbursement payments for generic drugs would still be significantly higher that providers' actual costs. Joint SOF at ¶ 58. In fact, when the proposal was initially made, DHS officials understood that payments under the new methodology would result in average margins – or "spreads" in California's parlance – of 180 percent for generic drugs. Joint SOF at ¶ 55.

E. 9th Circuit Injunctions Against Reimbursement Rate Reductions

In 1997, the Ninth Circuit enjoined DHS from reducing the rates it reimburses hospitals for providing outpatient services to Medi-Cal beneficiaries. *Orthopaedic Hosp. v. Belshe*, 103 F.3d 1491, 1500 (9th Cir. 1997), *cert. denied*, 522 U.S. 1044 (1998). The Ninth Circuit held that federal law requires DHS to perform studies to ensure that any revisions to Medi-Cal reimbursement rates are consistent with the goals of efficiency, economy, quality service, and access.[4] The Ninth Circuit affirmed this holding earlier this year when it enjoined a ten percent reduction in all Medi-Cal reimbursement payments, including payments to pharmacies, on the grounds that DHS failed to perform the required rate study to determine whether the new payments would be consistent with efficiency, economy, and access to quality care. *See Indep. Living Ctr. of S. Cal., Inc. v. Maxwell-Jolly*, 572 F.3d 644 (9th Cir. 2009). In its opinion, the Ninth Circuit explicitly rejected DHS's argument that the state's budgetary woes justified the rate cut:

> State budgetary considerations do not therefore, in social welfare cases, constitute a critical public interest that would be injured in the grant of preliminary relief. In contrast, there is a robust public interest in safeguarding access to health care for those eligible for Medicaid, whom Congress has recognized as the most needy in the country.

[4] The Central District of California relied on the Ninth Circuit's holding in *Orthopaedic Hospital* when it enjoined the five percent rate reduction to pharmacy reimbursement payments earlier this year. *See* Robben Decl. Ex. 46, at 7-8.

Id. at 659.

* * *

As the above evidence makes clear, issues of fact abound on each of the elements as to which California seeks summary judgment. Issues of material fact preclude summary judgment on the question of causation. In light of the evidence of California's informed decisions regarding reimbursement methodologies, a jury could reasonably conclude that California's continued deliberate reliance on a reimbursement methodology it knew paid providers more than their actual costs was the proximate cause of what it alleges in this action are "false" reimbursement claims. Furthermore, California has not demonstrated falsity as a matter of law, as it has failed to adduce an objective standard against which Defendants' AWPs could reasonably be said to be false. The "plain meaning" definition of AWP California urges the Court to adopt is simply not applicable in this case, given the evidence that California itself never understood AWPs to be actual proxies for prices paid in the market place, and deliberately structured reimbursement methodologies based on that understanding. Moreover, California has not demonstrated *scienter* as a matter of law, because evidence shows that Defendants (and California, for that matter) never believed, nor ever should have believed, that the AWPs reported in compendia for their generic drugs should approximate actual prices paid by providers.

Finally, California's attempt to pigeonhole evidence of its policy choices about Medi-Cal reimbursement as a "government knowledge" affirmative defense fails. This evidence is not restricted to an affirmative defense at all, but rather raises issues of fact on central elements of California's CFCA claim, namely causation, falsity, and *scienter*.

ARGUMENT

I. ISSUES OF FACT EXIST AS TO CAUSATION

California has failed to establish causation as a matter of law. California does not dispute that Defendants did not actually submit the allegedly "false" claims for reimbursement. Thus, Defendants are liable only if California can establish that Defendants "knowingly … cause[d] to be presented to an officer or employee of the state or of any political subdivision thereof, a false claim for payment or approval." CAL. GOV'T CODE § 12651(a)(1). To show that Defendants "caused" the submission of a false claim, California must demonstrate that Defendants' conduct was a proximate cause of the false claim. *United States ex rel. Drescher v. Highmark, Inc.*, 305 F. Supp. 2d 451, 460 (E.D. Pa. 2004). Under a proximate cause analysis, Defendants are not liable for claims that were the result of an intervening cause. *See United States ex rel. Cantekin v. Univ. of Pittsburgh*, 192 F.3d 402, 416 (3d Cir. 1999) (applying intervening cause analysis to FCA claim).

California contends that causation of the submission of false claims is satisfied by the following simplistic formulation: (a) Defendants reported AWPs for the Subject Drugs to pricing compendia; (b) the compendia AWPs did not approximate providers' actual costs; (c) California relied on the compendia AWPs to calculate payments for reimbursement claims submitted by Medi-Cal providers; thus (d) Defendants "caused" the submission of "false claims." This is not sufficient to establish causation as a matter of law because it ignores critical facts that a jury could reasonably conclude are intervening causes that break the attenuated causal link between Defendants' price reporting practices and the submission of what California now contends in this action are "false claims."

A. Defendants Have No Control Over Medi-Cal's Reimbursement Methodology

California's reimbursement methodology was established and controlled by California, subject to approval by the federal government. Joint SOF at ¶¶ 4-5. Defendants had no control over the methodology California chose to implement, nor did Defendants have any control over which method of reimbursement California chose to use for each claim. Moreover, nothing obligated California to rely on compendia AWPs to determine reimbursement payments. Yet the record demonstrates that California chose to implement reimbursement methodologies that it knew would pay providers more than their actual costs for drugs, especially for generic drugs, to ensure access to quality medical care and create an incentive for the use of lower cost drugs. From this evidence, a jury could reasonably conclude that the submission of the alleged "false claims" – which are nothing more than certain claims that were calculated based on compendia AWP and exceeded providers' actual costs – were proximately caused by deliberate policy decisions by California, not Defendants' price reporting practices.

B. Controlling Ninth Circuit Precedent Required California to Pay the Prices It Paid for the Subject Drugs

As discussed above, since January 1997, Ninth Circuit precedent has prohibited California from reducing Medi-Cal reimbursement rates without first ensuring that the new rates will be consistent with efficiency, economy, and access to quality care. *See supra* at 12. Even though California understood from well before that date that its reimbursement methodology of AWP minus five percent paid pharmacy providers significantly more than their actual costs to acquire drugs – especially generic drugs – California chose not to lower its reimbursement methodology for five years, citing as a critical concern that reducing rates may drive pharmacy providers from the program and deprive Medi-Cal beneficiaries of access to medical care. *See supra* at 10-11. After it received the Myers and Stauffer report in 2002 (which confirmed that

generic drugs could be purchased at a fraction of compendia AWP and showed spreads of more than 1000 percent for many generic drugs, including many of the Subject Drugs), it adopted only modest reductions to its reimbursement payments, first in 2002 with the move to AWP minus 10 percent and then again in 2004 with the move to AWP minus 17 percent. *See supra* at 11. California understood that these reductions would still result in reimbursement payments that far exceeded providers' actual acquisition costs for generic drugs, but nonetheless chose to adopt them, noting that deeper reductions may impair access to care. *See supra* at 11-12.

As recently as this year, the Ninth Circuit affirmed an injunction from implementing an across-the-board ten percent reduction in Medi-Cal reimbursements for all services, and the Central District of California has enjoined a five percent reduction in Medi-Cal pharmacy reimbursement, on the grounds that the reduced payments would impair access to quality medical care. *Maxwell-Jolly*, 572 F.3d 644; Robben Decl. Ex. 46. From these facts, a jury could reasonably conclude that the submission of what California now alleges are "false claims" was proximately caused by California's obligations under federal law to ensure access to quality care because, regardless of the prices reported by Defendants, the payments California made for the Subject Drugs were at the level California believed was necessary to ensure access to quality care and that California's use of compendia AWP as an element of its reimbursement formula was a deliberate policy choice made with full knowledge that the resulting payments would exceed acquisition costs and compensate Medi-Cal providers for the insufficient dispensing fees paid.

C. Defendants Have No Control Over the FULs Set by CMS

In its decision on Defendants' motion to dismiss this action, the MDL Court allowed California to seek recovery for reimbursement claims for the Subject Drugs that were paid on the basis of a Federal Upper Limit ("FUL") on the grounds that the regulations governing the

establishment of FULs – which provided that a FUL would be set at 150 percent of the lowest published price for a particular drug when three or more therapeutically equivalent versions of the drug were available – indicated that a predictable and formulaic relationship existed between FULs and published prices for the Subject Drugs. *See In re Pharm. Indus. Average Wholesale Price Litig.* (*State of California ex rel. Ven-A-Care of the Florida Keys, Inc. v. Abbott Labs, Inc.*), 478 F. Supp. 2d 164, 180 (D. Mass. 2007). However, as discussed in Defendants' Joint Brief in Support of their Motions for Partial Summary Judgment, subsequent discovery developed in the MDL demonstrates that CMS officials had broad discretion in establishing FULs, and that the FULs they implemented generally did not follow the predictable formula set forth in the FUL regulation. *See* Joint Brief at 26-29. Accordingly, at the very least, a jury could reasonably conclude that there is not a sufficient causal link between Defendants' price reporting practices and reimbursement payments for the Subject Drugs made on the basis of a FUL.

In the same vein, evidence developed in the MDL shows that the CMS officials would frequently not implement a FUL for a group of therapeutically equivalent products when the regulatory criteria for implementation of a FUL were met, or would discontinue a FUL even though a particular drug still qualified for one. Joint SOF at ¶¶ 88, 90, 92. Similarly, California could have established state maximum allowable costs for many of the Subject Drugs, as other states had done. Although California did implement what it called Maximum Allowable Ingredient Costs ("MAICs") for certain drugs, its MAIC program was not nearly as extensive as other states' MAC programs.[5] As Myers and Stauffer observed in its report in 2002:

[5] The MDL Court previously dismissed California's claims for drugs reimbursed on the basis of MAIC in its decision on Defendants' 12(b) motion, on the grounds that California failed to adequately allege a causal link between Defendants' price reporting practices and payments made based on MAICs. *In re Pharm. Indus. Average Wholesale Price Litig. (State of California ex rel. Ven-A-Care of the Florida Keys v. Abbott Labs)*, 478 F. Supp.2d at 180.

> As compared to MAC systems observed in other states, Medi-Cal's MAIC prices have not been set for a broad range of multi-source drugs. An expansion of MAIC pricing to cover a more comprehensive set of multi-source drugs might be desirable. If an expansion of MAIC pricing expansion [*sic*] is considered, we would recommend that rates be based upon observations of pharmacies' actual acquisition cost incorporating appropriate margins to assure cost coverage.

Robben Decl. Ex. 33, at p. 6. Again, at the very least, a jury could reasonably conclude that the CMS's failure to establish a FUL, or California's failure to establish a MAC, for an otherwise qualifying Subject Drug, was the proximate cause of what California contends was a false claim for that drug.

II. CALIFORNIA HAS NOT SHOWN FALSITY AS A MATTER OF LAW

A. California Has Not Demonstrated "Falsity" Because It Has Not Produced Evidence of an Objective Standard Against Which Defendants' AWPs Can Be Assessed

A claim for payment is not "false" unless it is made in violation of an objective controlling rule, regulation, or standard. *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1026 (D. Nev. 2006); *United States ex rel. Cox. v. Iowa Health Sys.*, 29 F. Supp. 2d 1022, 1026 (S.D. Iowa 1998). For instance, in *United States ex rel. Local 342 Plumbers & Steamfitters v. Dan Caputo Co.*, 321 F.3d 926 (9th Cir. 2003), the relator brought a False Claims Act claim against a subcontractor performing work on a federally funded project, alleging that the subcontractor falsely certified that it was paying its employees the prevailing wage, pursuant to federal law, when in fact it was not. *Id.* at 927. The Ninth Circuit affirmed summary judgment in favor of the subcontractor, holding that the relator had failed to establish falsity because it had failed to show that the subcontractor was not paying the prevailing wage, as there was no showing of what the prevailing wage was. *Id.* at 933. California likewise has not established "falsity" as a

matter of law because there is no evidence of a controlling rule, regulation, or standard from which it could be determined that Defendants' AWPs were "false."

California never defined AWP in a statute or regulation as anything other than a price that appeared for a particular drug in a pricing compendia, which is what Defendants' AWPs are. *See* Joint SOF at ¶ 20. On this criterion, there is no basis to hold that Defendants' AWPs were false. In its moving papers, California has failed to adduce any other evidence of an objective standard for AWP against which Defendants' AWPs could be assessed.

If California had intended that Defendants report as AWPs actual averages of prices paid in the market place for their drugs, it could have defined the term in a statute or regulation as such. Indeed, as discussed above, other terms used in the Medicaid context, such as AMP, ASP, and WSP, are defined in statute in a manner that offers guidance as to how they should be determined and what they should reflect. *See supra* at 3-5. In light of the contradictory evidence, a jury should be the one to determine the credibility of California's witnesses who will presumably testify (contrary to the documentary record and deposition admissions of California officials) that California used AWP as a "proxy for real world prices paid by providers." *See* Opp. at 7.

B. <u>There is No Support for California's "Plain Meaning" Definition of AWP</u>

Apparently recognizing the absence of any objective standard in the record against which Defendants' AWPs can be evaluated, California argues that the term "AWP" as it is used in the statutes and regulations governing California's reimbursement methodology should be given a "plain meaning" definition, *i.e.* that it should mean an actual average of wholesale prices for the subject drugs or some other approximation of prices actually paid. However, the very federal regulation California cites to support this argument, as well as the evidence in the record, contradict this contention.

California's contention that the federal EAC regulations require it to pay providers nothing more than a best estimate of the provider's actual cost for a drug, on a drug by drug basis, is wrong. As discussed above, the regulations merely placed limits on California's reimbursement payments in the aggregate across all drugs for both the ingredient portion and the dispensing fee payments, and were intended to allow states considerable flexibility in setting reimbursement rates for individual drugs to meet various policy goals, including the promotion of the use of multi-source drugs. *See supra* at 8-10. HCFA expressly contemplated and promoted the use of undiscounted "benchmark" prices to calculate reimbursement precisely because they would result in margins for multi-source drugs. Thus, California's contention that, in light of these regulations, its use of AWP in its reimbursement methodology requires that AWP be given a "plain meaning" is unsupportable.

Indeed, California's choice of reimbursement methodologies since then has been entirely consistent with the "in the aggregate" provisions of the 1987 regulations and the goals HCFA articulated when it adopted them. The record evidence clearly demonstrates California has understood – since at least the late 1970s – that AWP significantly exceeded providers' actual acquisition costs, especially for generic drugs. Moreover, the evidence set forth above shows that California never intended its payments to approximate actual acquisition costs for generic drugs. Rather it intentionally chose to base reimbursement payments on only modest discounts from AWP to meet certain policy goals, including ensuring that Medi-Cal beneficiaries had adequate access to care, promoting the use of generic drugs, and compensating providers for inadequate dispensing fees.

C. The MDL Court's Prior Ruling on the Definition of AWP in the Medicare Context is Not Relevant in this Case

To support its argument for a "plain meaning" of AWP, California urges this Court to simply readopt the MDL Court's decision in a class action case brought on behalf of consumers and private third-party payors holding that the term "average wholesale price" as it is used in a federal statute governing the Medicare program should be given a "plain meaning," and apply the same "plain meaning" definition to AWP as it is used in the California statutes and regulations governing pharmacy reimbursement under the Medi-Cal program. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277 (D. Mass. 2006); Opp. at 6. However, the mechanical reapplication of the definition in that case to the facts of this case is untenable.

First, the MDL Court made it clear that the decision was limited to the context of that case. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 279, n. 1 ("In addition to the private class action, several states, counties, and cities have also brought actions against the pharmaceutical manufacturers for fraudulent inflation of AWP. The multidistrict litigation before this Court includes such actions from Arizona, *California*, Nevada, and New York. … The Court does not address these actions here.") (emphasis added). Indeed, the MDL Court limited its analysis to the use of the term AWP in the context of Medicare reimbursement and made no attempt to determine how the term "AWP" should be construed in the Medicaid context.

Second, the issues before the Court in this action are readily distinguishable from the issues before the MDL Court in the action where it rendered its "plain meaning" definition. In that action – a class action that was brought on behalf of individual consumers and third-party payors who were allegedly caused to make overpayments on Medicare co-pays as a result of

allegedly "inflated" AWPs – the MDL Court had to determine whether AWPs that were used to calculate the Medicare co-pay amounts were "deceptive and unfair" under the Massachusetts Consumer Protection Act, which (unlike the CFCA) does not require an objective untruth. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp.2d 20, 80 (D. Mass. 2007).[6] In contrast the issue in this action is whether Defendants AWPs are "false" for the purposes of the CFCA in the context of reimbursement under the Medi-Cal program, when California has only ever defined AWP as a price listed in a compendia, the federal regulations governing California's reimbursement methodology specifically anticipate that payments will be made based on published benchmark prices that exceed providers' actual acquisition costs, and evidence shows that Medi-Cal has made policy choices to make such payments throughout the relevant time period and continues to do so today. *See supra* at 10-12.

Third, in rendering its decision, the MDL Court drew heavily on an *amicus* brief submitted by the United States Department of Justice ("DOJ") which purported to show the United States Department of Health and Human Services' ("HHS") position regarding AWP. *See* Docket No. 3104. The United States, however, was not a party to that action, and invoked HHS's *Touhy* regulations to bar any discovery to test the factual assertions made in the DOJ's *amicus* brief. In contrast, the record in this action is replete with evidence that California not only understood that AWPs were not actual approximations of providers' cost, but chose to reimburse using AWPs to meet its own policy goals. *See AstraZeneca L.P. v. State*, No. 1071439, 2009 WL 3335904, at *24, n. 9 (Ala. Oct. 16, 2009) ("The State also relies on

[6] Moreover, unlike here where California contends that Defendants' liability should rest solely on the "plain meaning" of AWP, liability in the class action did not turn on the "plain meaning" of AWP as used in the Medicare statute at all, but rather on the question of whether the "spreads" between providers' actual acquisition costs and published AWPs for physician-administered brand name drugs exceeded industry expectations which the MDL Court determined to be 30 percent for that particular category of drugs after trial. *See Blue Cross Blue Shield of Mass. v. AstraZeneca Pharm. LP*, 582 F.3d 156, 171-72, 178-80 (1st Cir. 2009).

dictionary definitions of the words included in the terms WAC and AWP and argues that the 'plain meaning' of the words supports its position. However, any relevance the 'plain-meaning' rule might have had in this dispute is negated by the State's actual knowledge of a different meaning.")[7]

III. QUESTIONS OF FACT EXIST AS TO DEFENDANTS' SCIENTER

"[I]t is unusual to grant summary judgment on scienter except in cases where the nonmoving party rests merely upon conclusory allegations, improbable inferences, and unsupported speculation." *Massachusetts v. Mylan Labs.*, 608 F. Supp. 2d 127, 154 (D. Mass. 2008) (Saris, J.) (*quoting S.E.C. v. Ficken*, 546 F.3d 45, 51 (1st Cir. 2008)). This is not one of those unusual cases. Because there is evidence in the record that Defendants never believed or had reason to believe that California used AWPs to approximate actual acquisition costs, California's motion on this ground must fail.

To establish the *scienter* required under the CFCA, California must show that Defendants acted with actual knowledge, deliberate ignorance, or reckless disregard when reporting AWPs to compendia. *See* CAL. GOV'T CODE § 12650(b)(2). It is not sufficient to show an innocent mistake, negligence, or even gross negligence. *United States ex rel. Farmer v. City of Houston*, 523 F.3d 333, 341 (5th Cir. 2008) ("[T]he *mens rea* requirement [of an FCA claim] is not met by mere negligence or even gross negligence.") In its attempt to establish Defendants' *scienter*, California alleges that Defendants knew that their published AWPs were "untethered to any measure of actual average acquisition costs." *See* Opp. at 23. California further argues that the term "AWP", as used in California regulations and statutes, is meant to reflect providers' actual acquisition costs. *Id.* However, the summary judgment record shows that issues of fact abound

[7] Defendants note that a certificate of judgment has not yet been entered in that action, and that an application for rehearing is pending before the Alabama Supreme Court.

as to *scienter* since Defendants never understood that California intended AWPs to be an approximation for providers' actual acquisition costs, nor did they ever have any reason to understand as much.

A. California Has Failed to Demonstrate as a Matter of Law that Defendants Had Reason to Believe That Compendia AWPs Should Approximate Actual Acquisition Costs

California has failed to adduce any evidence that Defendants should have known that California expected that AWPs published in pricing compendia would approximate providers' actual costs. In fact, the evidence demonstrates just the opposite.

In contrast to other pricing terms such as AMP, ASP, and WSP, which are all defined in statute in a manner that gives clear guidance as to how they should be calculated, California has never defined the AWP that it uses in its reimbursement methodology as anything other than a price listed in a compendium. Defendants had no reason to believe that AWP, an undefined term, should reflect a fully discounted market price when AMP (which has been defined in federal statute and the Rebate Agreement since 1991), ASP, and WSP were all expressly defined in that manner. Moreover the notion that Defendants should have understood the AWPs they reported to pricing compendia for publication were intended to be fully discounted transaction prices is untenable, considering that they were already reporting AMPs directly to CMS as part of the Medicaid program and were being invoiced by California for rebates based on those AMPs.

Furthermore, California's own reimbursement methodology belies its argument that Defendants knew that California viewed AWP as an actual acquisition cost. Indeed, throughout the relevant time period, California never reimbursed providers at a given drug's AWP, but instead always deducted a percentage from a given drug's AWP when calculating reimbursements, moving its reimbursements from AWP minus 5 perent to AWP minus 10

percent and ultimately to AWP minus 17 percent. Joint SOF at ¶ 19. Thus, assuming that Defendants knew the details of California's reimbursement methodology (as California alleges), a jury could reasonably conclude that Defendants would know that California applied percentages off of AWP when calculating reimbursements (and reasonably reject the notion that California was actually laboring to make participation in Medi-Cal an increasingly money-losing endeavor for pharmacies). In light of California's ever-deeper discounting of AWP, Defendants could not know or believe that California viewed AWP as an actual acquisition cost.

Finally, California itself never understood AWPs to actually reflect prices paid in the marketplace for drugs. Rather, California knew well that AWPs significantly exceeded providers' actual costs both for generic drugs, generally, and for many of the Subject Drugs at issue. "Government knowledge" vitiates the requisite *scienter* under the CFCA: "there cannot be a knowing presentation of a false claim for payment where the government is fully aware of the facts surrounding the claim and approves it." *United States v. Shasta Servs. Inc.*, 440 F. Supp. 2d 1108, 1113 (E.D. Cal. 2006). As discussed above, California has known since at least the late 1970s that compendia AWPs significantly exceed providers' actual acquisition costs. The notion that Defendants should have believed California intended AWPs to represent actual cost because California used them in its reimbursement methodology – when California's own witnesses testified that Medi-Cal reimbursement payments contain a "significant profit" to the provider – is untenable. *See* Joint SOF at ¶ 67.

B. Defendants Did Not Believe that AWP Should be an Approximation of Actual Acquisition Costs

California has failed to adduce any evidence that Defendants actually understood that their AWPs should reflect actual market prices, or that they believed they were deceiving California by reporting AWPs in the manner they did. In contrast, Defendants have produced

ample evidence in the record demonstrating that Defendants understood that, for generic drugs, AWP was an undiscounted benchmark price that was set in relation to published prices for therapeutically equivalent drugs, and was not intended, particularly by California, to approximate a provider's actual cost to acquire a drug. This evidence alone creates a genuine issue of material fact on the issue of scienter such that summary judgment is inappropriate.

1. Sandoz

For example, Christopher Worrell, Sandoz' former Vice President for Sales and Marketing, testified that it was his understanding while working at Sandoz that AWP was merely a benchmark price and not an approximation of a price that pharmacies would pay to acquire Sandoz drugs. The Sandoz AWP was set at approximately 90% of the AWP for the corresponding brand name drug product of the same chemical form and dosage. The only reason for setting AWPs at this level was to insure that Sandoz products would be classified as a generic drug product by the pricing compendia. By contract, actual transaction prices were established by competition among generic manufacturers in the open market. Deposition of Christopher Worrell, dated August 23, 2007, at 48:8 - 49:5. Sandoz set AWPs for its products and provided these AWPs to the pricing compendia, for the relevant time period in accordance with its understanding of the use of the term in the industry, and that Sandoz AWPs were not in any way false, deceptive, or misleading. *See, e.g.*, 8/23/2007 Worrell Dep. 183:5-23. Every other Sandoz witness has testified similarly. These AWPs were not intended to be actual average prices by Sandoz, and were not understood to be actual average prices by the compendia or California. *See, e.g.*, Deposition of Kevin Galownia, dated June 11, 2007, at 113:6-9; 114:6-9; 220:16-221:2; 387:15 - 388:6 and deposition of Armando Kellum, dated January 25, 2007 at 79:1-14.

In addition to reporting AWPs, Sandoz also provided pricing compendia with Wholesale Acquisition Costs ("WACs"), for its drugs throughout the relevant time period. Sandoz Counterstatement at Resp. 7. Sandoz' WAC is the invoice price for all its transactions with wholesalers. *See*, 8/23/2007 Worrell Dep. 82:5-17. Further, beginning on July 16, 1991, Sandoz voluntarily provided the State of California with its AMP data – the "net prices to wholesalers and distributors" that takes into account all discounts, rebates, chargebacks and any other price adjustments – for every drug reimbursed by Medi-Cal on an NDC by NDC basis. *See* (Letter from Beth Brannan, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to Michael Neff, California Dept. of Health Services enclosing AMP data, dated July 16, 1991 (SANDOZ CALI 3000033)) attached as Tab [] to the Declaration of Catherine Castaldo in Support of Sandoz Inc.'s Response to Plaintiffs' Local Rule 56.1 Statement of Undisputed Facts as to Sandoz Inc.; *see also* (Takeuchi Tr. at 145:3 -22). Sandoz continued to directly provide the State of California with its AMP data until March 21, 1997. See (Letter from Ron Hartmann, Manager, Government Affairs, Geneva Pharmaceuticals, Inc. (Sandoz) to State of California enclosing AMP data, dated Mar. 21, 2007 (SANDOZ CALI 3001109)). If California had ever actually wanted to review or utilize actual transaction prices, it only had to look at the very data that Sandoz provided it. Finally, like all other drug manufacturers whose participate in the Medicaid program, Sandoz has also reported its AMPs to CMS on a quarterly basis for all other time periods. Sandoz Counterstatement at Resp. 13.

Moreover, Sandoz' representatives attended numerous meetings with officials from Medi-Cal and believed that those officials all understood that AWPs were not actual averages. Deposition of Ronald Hartmann, dated May 10, 2009, at. 337:16 - 341:12. Neither the compendia nor California ever told Sandoz that it expected AWP to be an actual average price.

Galownia, 6/11/2007, 387:15 - 388:6. In fact, First DataBank repeatedly told its own customers that AWP was referred to as "ain't what's paid." Deposition of Donovan, dated July 20, 2009, Tr. 355: 5-20; Exhibit 15 (FDB Presentation re: Pricing Methodologies), Bates # HI_HI000002693.

2. Mylan

Similarly, evidence indicates that Mylan understood AWP to be a benchmark indicator of whether a drug was a brand or generic, not an actual approximation of prices paid by pharmacies to purchase Mylan's drugs. Brian Roman, Mylan's 30(b)(6) designee, testified that it was Mylan's practice to set its AWPs in a manner that would indicate that its drugs were generics, which meant either setting them at a discount off of the published AWP for the therapeutically equivalent brand drug when Mylan's product was the first generic entrant, or at a price within the range of published AWP for other generics, when other generic versions were already available. Mylan Counterstatement at Resp. 7.

In addition to reporting AWPs, Mylan also provided pricing compendia with Wholesale Acquisition Costs ("WACs") for its drugs throughout the relevant time period. Mylan Counterstatement at Resp. 7. Mylan's WAC is the invoice price for all its transactions with wholesalers, which comprises a large part of its business. *Id.* Like all drug manufacturers whose drugs are reimbursed under the Medicaid program, Mylan has also reported its AMPs – the "net prices to wholesalers and distributors" that take into account discounts, rebates, chargebacks and any other price adjustments – to CMS on a quarterly basis. Mylan Counterstatement at Resp. 10. Thus, the notion that Mylan believed that it was keeping its actual transaction prices a secret is simply not tenable.

Moreover, in one of the few instances in which California did have direct communications with Mylan concerning pricing, California made it clear that it actually

expected "mega-spreads" between published prices and prices actually paid for generic drugs. On July 17, 2002, Mike Namba from Medi-Cal emailed Eric Belldina at Mylan a spreadsheet with various examples of supplemental rebate agreements to illustrate how Medi-Cal negotiated net-cost supplemental rebate contracts. Mylan Counterstatement at Resp. 19. One of the examples is for a Net-Price Supplemental Rebate Agreement for a generic drug. *Id.* The calculations in the example show that, for a drug with AWP of $3.00 not subject to a FUL or MAIC, Medi-Cal's lowest price per capsule is $2.85 (AWP-5%). *Id.* The AMP, "as reported to HCFA," is $0.50. *Id.* The illustration proceeds to determine Medi-Cal's Net Price, stating that "[i]n this example, Medi-Cal agrees to add a drug to the List if the manufacturer will guarantee that Medi-Cal's price will be $2.00 per capsule. *Since the AWP is inflated*, the manufacturer must rebate a very large amount to reach the net price." *Id.* (emphasis added). Through this spreadsheet, California communicated to Mylan not just that it expected an AWP for a generic drug to be "inflated" but that it expected a "spread" between the published AWP and the AMP reported by the manufacturer of 500 percent. Importantly, this was not a complaint, but in fact an instruction.

3. Dey

Like Sandoz and Mylan, the evidence demonstrates that Dey understood AWP to be a benchmark indicator of a drug's status as a generic, not an approximation of actual prices paid for Dey's drugs. Dey's Chief Financial Officer, Pamela Marrs, testified that Dey had been instructed by Ed Edelstein of First DataBank to set the AWPs for its generic products at a discount off the AWP for therapeutically equivalent brand products. Dey Counterstatement at Resp. 8. Ms. Marrs testified that she understood this was consistent with industry practice. *Id.*

Moreover, starting in 1999, Dey made it explicitly clear to Medi-Cal that its AWPs were not actual transaction prices for Dey's drugs. Starting in 1999, Dey began sending letters to officials at Medi-Cal and other state Medicaid programs that stated the following:

> … [A]s you … know, the Average Wholesale Price (or "AWP") per unit listed above does not represent actual wholesale prices which will be charged or paid for this product. It is Dey's practice to set an AWP before a product is first sold and not subsequently to change that figure. We understand that this is consistent with industry practice and is understood by state and federal Medicaid regulators.

Dey Counterstatement at Resp. 10. The letters also contained a telephone number that Medi-Cal could call in case there were questions. *Id.* Mr. Gorospe recalled receiving letters from manufacturers with disclosures like this and testified that, in 1999, the description of how Dey set its AWP would not have caused him any concern. *Id.*

Moreover, Dey regularly updated the WACs it reported to pricing compendia to directly reflect underlying pricing activity for its drugs. Dey Counterstatement at Resp. 7. As the prices for Dey's drugs in the market place declined, the WACs Dey provided the compendia declined. *Id.* Like all drug manufacturers whose drugs are reimbursed under the Medicaid program, Dey also reported its AMPs – the "net prices to wholesalers and distributors" that take into account discounts, rebates, chargebacks and any other price adjustments – to CMS on a quarterly basis. *Id.* Thus, the notion that Dey believed that it was keeping its actual transaction prices a secret is simply not tenable.

* * *

California's attempt to distinguish the current case from this Court's prior holding on the issue of scienter is unavailing. *See* Opp. at 23. As with the defendants in *Mylan*, Defendants here have produced sworn testimony that they believed AWP was simply a benchmark price. *See Mylan*, 608 F. Supp. 2d at 154-55; *supra* at 25-30. Furthermore, as with the defendants in

Mylan, Defendants have pointed to evidence that California understood that AWP did not represent actual acquisition costs. *Id.*; *see supra at* 24-25. Consequently, as this Court held in *Mylan*, when viewing all facts in the light most favorable to Defendants, it is clear that "the issue of defendants' knowledge will have to be resolved drug by drug…and depend[] on numerous factors," such that summary judgment at this stage is inappropriate. *See Mylan*, 608 F. Supp. 2d at 155.

IV. CALIFORNIA'S ARGUMENTS CONCERNING "GOVERNMENT KNOWLEDGE" ARE MERITLESS

A. Defendants Do Not Have the Burden of Establishing a "Government Knowledge" Affirmative Defense

California reductively characterizes evidence of its knowledge that AWPs (both generally and as to the specific AWPs for the Subject Drugs) do not reflect prices paid by Medi-Cal providers and that its reimbursement payments for the Subject Drugs exceeded providers' actual acquisition costs as the "government knowledge defense"; from this false premise, California goes on to argue that this "defense" is not applicable in this action and that there is not sufficient evidence in the record to support this "defense." In fact, while some courts refer to a government knowledge "defense," evidence of the government's knowledge of the false nature of a claim is not part of an affirmative defense but, rather, negates elements of California's CFCA claims directly. *See San Francisco Bay Area Rapid Transit Dist. v. Spencer*, No. C 04-04632 SI, 2007 WL 1450350, at *8 (N.D. Cal. May 14, 2007) ("Though it is not an affirmative defense, government knowledge is not irrelevant [to a CFCA claim]"). As at least one court has observed in the federal FCA context, "This defense is inaptly named because it is not a statutory defense to FCA liability but a means by which the defendant can rebut the government's assertion of the 'knowing' presentation of a false claim. Inevitably, the extent of the

government's knowledge is also bound up with whether the claim itself was false." *U.S. v. Southland Mgmt. Corp.*, 326 F.3d 669, 682 n. 8 (5th Cir. 2003) (Jones, J., concurring).

Here, California's knowledge that AWPs exceed providers' acquisition costs is directly relevant not only to the elements of falsity and *scienter*, but also to the purported causation of the submission of false claims and causation of damages. As noted above and in Defendant's Joint Brief in Support of their Motions for Summary Judgment, both the causation of the submission of claims and the causation of damages in the CFCA context are governed by the "proximate cause" standard. A jury could reasonably conclude that California's continued reliance on AWPs to calculate reimbursement despite its knowledge that AWPs significantly exceeded acquisition was the "proximate cause" of the submission of alleged false claims and of the damages California seeks to recover. *See supra* at 14-18; Joint Brief at 15. However, all of these elements are questions of fact that should be resolved by the jury.[8] By moving for summary judgment on the "government knowledge defense" California is attempting to improperly dispose of key evidence that withers its claims by miscasting government knowledge as a straw affirmative defense, and shifting the burden to Defendants to establish the elements of this "defense." In reality, exactly the opposite is true; the extensive evidence of California's understanding of AWP is something that California must rebut if it is to obtain summary judgment. This, of course, California has not done. The Court, therefore, should reject California's gambit.

[8] Defendants have moved for summary judgment on, among other grounds, the limited ground that California's knowledge concerning providers' actual acquisition costs for the Subject Drugs was so complete by August of 2002 that California could not possibly establish falsity or *scienter* under the CFCA after that date. However, evidence of California's knowledge concerning the relationship between AWP and providers' costs from before that date undermines California's CFCA claims as well, as Defendants will demonstrate at trial.

B. Evidence of California's Knowledge Concerning AWPs and Actual Costs for the Subject Drugs is Relevant in the Medicaid Context

California argues that government knowledge evidence is not relevant in the Medicaid reimbursement context because, unlike the context of an individual government contract, even if California was fully informed of the exact differences between AWP and actual acquisition cost for all of the subject drugs for each claim it paid, it was still obligated to reimburse "pursuant to the governing standards." This argument is illogical and unsupported, as California was never required by any federal law or regulation to rely on published AWPs, but rather chose to do so for its own policy purposes.[9]

At the federal level, there was no requirement that Medi-Cal calculate reimbursement based on compendia AWP. In fact, several states did not. Rather, federal regulations merely placed limits on California's total reimbursement payment for all drugs in the aggregate, while at the same time ensuring that payments were consistent with efficiency, economy, and access to quality care. *See supra* at 8-10. Indeed, as discussed above, the governing regulations were specifically designed to allow California to pay more than a provider's actual cost and were intended to encourage payment of profit margins for generic drugs like the subject drugs. *Id.* The argument that federal regulations governing Medicaid reimbursement somehow obligated

[9] Not surprisingly, California cites no authority that supports its contention that government knowledge is irrelevant in the context of Medicaid payments. *United States v. Estate of Rogers*, No. 1:97CV461, 2001 WL 818160, at *4 (E.D. Tenn. June 28, 2001) and *United States ex rel. Oliver v. Parsons Co.*, 195 F.3d 457, 463 (9th Cir. 1999) stand for the proposition that submission of a claim based on a reasonable, albeit improper, interpretation of a statute or regulation does not necessarily foreclose a finding of falsity under the federal FCA. *Brown v. State Department of Health*, 86 Cal.App.3d 548, 555 (Cal. Ct. App. 1978) stands for a similar proposition, but in the context of a disciplinary proceeding against a physician, not an FCA claim. In *United States v. Schiavone*, 430 F.2d 231, 233 (1st Cir. 1970), the First Circuit held that the United States' possible knowledge concerning the potential illegality of a lease, and its failure to act thereon, did not estop the United States from subsequently bringing a claim under the Elkins Act arising from the subsequent sale of the land that was covered by the lease. None of these cases discuss government knowledge in the context of a California or a Federal FCA claim at all, much less stand for the proposition that California's knowledge regarding the relation between AWP and providers' actual costs is irrelevant in this action.

California to continue reimbursing for the Subject Drugs based on AWP regardless of California's knowledge is baseless.

The argument fares no better concerning state-level statutes and regulations, as California enacted and promulgated those statutes and regulations itself. Throughout the relevant time period, California was free to increase the discounts it paid off of AWP, or move away from AWP as a basis for reimbursement entirely. Thus, if California was aware that AWPs for the subject drugs substantially exceeded providers' actual acquisition cost for the subject drugs (and evidence demonstrates that it was) it should easily have been able to address the issue by changing its reimbursement methodology. It is illogical to contend that California's failure to act in light of its knowledge is somehow not relevant to Defendants' liability in this action.

C. The Evidence of California's Knowledge Creates Substantial Questions of Fact

The evidence in the record of California's knowledge concerning the relationship between compendia AWPs and providers' actual acquisition costs is sufficient, at the very least, to create questions of fact as to the elements of falsity, scienter, and causation. California's arguments to the contrary misstate both the applicable law and the facts in evidence.

California contends that the evidence of its knowledge in the record is not sufficient to rebut the elements of its CFCA claims because there is no showing that Defendants ever communicated to California the actual acquisition costs for their drugs or the extent of the differences between those prices and the compendia AWP, on a specific, drug-by-drug basis. However, this is not the standard when considering evidence of government knowledge.

There is no requirement that California's knowledge must be obtained from Defendants in order to be relevant to elements of California's CFCA claims. For instance, in *United States v. Shasta Services, Inc.*, 440 F. Supp. 2d 1108, 1110, 1113 (E.D. Ca. 2006), the court found that the

California Department of Transportation's knowledge of the allegedly fraudulent nature of a contractor's bid precluded liability under the CFCA, even though that knowledge had been obtained through complaints by another contractor and the Department's own investigation, rather than from disclosures made by the defendant. Thus, there is no reason that knowledge California acquired through its own investigations or through reports issued by the federal government should be disregarded simply because Defendants did not supply it to California directly.

Nor is there a requirement that California's knowledge must be Defendant-specific or drug-specific to create a question of fact. For instance, in *Massachusetts v. Mylan Laboratories*, 608 F. Supp. 2d 127, 15-53 (D. Mass. 2008), the MDL Court held that an HHS-OIG publication that disclosed that pharmacies paid, on average, 30 percent below WAC to acquire generic drugs was sufficient to create a question of fact on Massachusetts False Claims Act claims to recover Medicaid reimbursement payments based on WACs, even though the report did not contain defendant-specific or drug-specific information and only discussed discounts off of WAC in average terms. Thus government reports documenting the differences between AWP and providers' acquisition costs are relevant to the CFCA claims in this action, even if they do not mention Defendants or the Subject Drugs by name.

Moreover, contrary to California's unsubstantiated assertions, there is evidence in the record that California had detailed information regarding the differences between compendia AWP and providers' actual cost both on a Defendant-specific and drug-specific level. For instance, Sandoz reported AMPs for each of its drugs reimbursed under the Medi-Cal program directly to DHS on a quarterly basis from 1991 to 1997. Sandoz Counterstatement at Resp. 18. In 2000, California received a list of approximately 400 "revised" AWPs, calculated by the

National Association of Medicaid Fraud Control Units and the United States Department of Justice based on surveys of actual market prices. Dey-SOF at 37. Included on the list were revised AWPs on a NDC-specific level for Dey's acetylcysteine, albuterol, cromolyn, and metaproterenol, all of which are Subject Drugs in this action. *Id.* Finally, in August of 2002, Myers & Stauffer issued a report documenting the results of its survey of providers' actual acquisition costs. Joint SOF at ¶ 44. The report contains side-by-side comparisons of AWPs and providers' actual acquisition costs for 78 of the Subject Drugs manufactured by Mylan, Dey, and Sandoz. Joint SOF at ¶ 45.

California also contends that evidence of its knowledge is irrelevant because there is no evidence that California ever expressly authorized Defendants to report AWPs to publishing compendia that did not reflect providers' actual acquisition costs. Again, California misstates the applicable law. The relevant question is whether California acquiesced in the payment of claims that exceeded providers' actual acquisition costs. *See, e.g.*, *United States ex rel. Englund v. Los Angeles County*, No. CIV. S-04-282 LKK/JFM, 2006 WL 3097941, at *12 (E.D. Cal. Oct. 31, 2006) (granting summary judgment for defendants because "the Federal government knew what [defendant] was doing and *implicitly* approved of [defendant's] actions") (emphasis added). California's contention that there must be some sort of express approval or authorization communicated by California to Defendants is simply wrong. *See, e.g.*, *United States ex rel. Burlbaw v. Orenduff*, 548 F.3d 931, 954 (10th Cir. 2008) ("[W]e conclude that neither the directness of the government-contractor communications nor their nexus to an existing contractual relationship constitute an essential predicate for the government knowledge inference.")

The record is replete with evidence of California's acquiescence in, and approval of, paying spreads on generic drug reimbursements. Indeed, as early as 1987, some seven years before the start of the relevant time period, California not only acknowledged that its adoption of the FUL regulations would result in the payment of margins for generic drugs, but specifically (and approvingly) pointed to an example where its reimbursement methodology would result in a "spread" of more than 100 percent. *See* Joint SOF at 26. Since that time, California has considered revising its reimbursement methodology several times, but each time has either rejected proposals that it knew would bring its payment levels closer to providers' actual costs, or implemented changes that it knew would still pay providers significant margins for generic drugs. *See* Joint SOF at ¶¶ 33, 35-36. In 2004, when California adopted the reimbursement methodology that is in place today, Medi-Cal officials knew that it would result in payments of margins of 180 percent on average for generic drugs, but endorsed it anyway. *See* Joint SOF at ¶ 55. Even today DHS officials acknowledge that Medi-Cal's chosen reimbursement methodology – which is still AWP minus 17 percent – results in payments to providers for drugs that are "well above pharmacy acquisition cost" and that providers receive a "significant profit on Medi-Cal reimbursement for the drug itself." Joint SOF at ¶ 67. California's adherence to a reimbursement methodology that it knew and intended would pay pharmacists what California claims are "mega-spreads" on generics is sufficient, at a minimum, to raise questions of fact on California's CFCA claims, such that California's motion for summary judgment should be denied.

CONCLUSION

For the reasons set forth above, Defendants respectfully request that the Court deny the Plaintiffs' Motion for Partial Summary Judgment.

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CERTIFICATE OF SERVICE

I certify that a true and correct copy of the foregoing was delivered to all counsel of record by electronic service pursuant to Paragraph 11 of Case Management Order No. 2, by causing to be sent, on December 21, 2009, a copy to LexisNexis File & Serve for posting and notification to all parties.

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